AUG 1 3 2010

Section 10. 510(k) Summary

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.
The Assigned 510(k) number is: **K092875**

1. Submitter's Identification:
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Prepared Date: September 14, 2009

2. Device name:
Proprietary name: TD-3227 Dual Blood Pressure/Blood Glucose Meter.
Regulatory information:
Regulation section: 21 CFR § 862.1345, Glucose Test System
21 CFR §870.1130, Noninvasive blood pressure measurement system
Classification: Class II (Glucose Test System)

Class II (Blood Pressure Measurement System)
Product Code: NBW, System, Test, Blood Glucose, Over The Counter

CGA, Glucose Oxidase, Glucose
DXN, System, Measurement, Blood-Pressure, Non-Invasive
Panel: 75, Clinical Chemistry – Glucose Test System

74, Cardiovascular – Blood Pressure Measurement System

3. Intended Use:

ECHO TD-3227 Dual Blood Pressure/Blood Glucose Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the following alternative sites: the palm, forearm, upper-arm, calf and thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. The alternative site testing in the systems can be used only during steady-state blood glucose conditions.
The system is also intended to measure non-invasively the systolic and diastolic blood pressure and pulse rate. For ECHO TD-3227 Dual Blood Pressure/Blood Glucose Meter, the blood pressure is measured by using a technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 5.31"- 8.66".
The device is not to be used for the diagnosis or screening of diabetes, hypertension or for testing on neonates.

4. Device Description:
The kit of ECHO TD-3227 Dual Blood Pressure/Blood Glucose Meter consist of four main products: the meter features both the blood glucose and blood pressure measurement functions, test strips, control solutions (cleared under k012430), and the lancet device (cleared under k833344). These products have been designed and tested to work together as a system to produce accurate blood glucose test results.

5. Substantial Equivalence Information:
Predicate device name:

Clever Chek TD-3217 Blood Glucose plus Blood Pressure Monitoring System.
Predicate K number: K062800
Comparison with predicate:

The modified ECHO TD-3227 Dual Blood Pressure/Blood Glucose Meter has the following similarities to the predicate device:

- same operating principle,
- same fundamental scientific technology,
- incorporate the same basic circuit design,

- incorporate the same materials,
- same shelf life
- packaged using the same materials, and
- Manufactured by the same process.

The modifications encompass:

- A modification in the software of the meter
- Modification in the physical appearance
- Expansion of cuff size
- Labeling change due to the software modification

6. Test Principle:

For blood glucose, the detection and measurement is by an electrochemical biosensor technology using glucose oxidase.
For blood pressure, the measurement is by using oscillometric, non-invasive blood pressure (systolic, diastolic and mean arterial pressure) measuring technology.

7. Performance Characteristics:
Software verification and validation testing confirmed that the performance, safety and effectiveness of ECHO TD-3227 Dual Blood Pressure/Blood Glucose Meter met acceptance criteria.

8. Conclusion:
Based on the information provided in this submission, ECHO TD-3227 Dual Blood Pressure/Blood Glucose Meter is substantially equivalent to the predicate Clever Clever Chek TD-3217 Blood Glucose plus Blood Pressure Monitoring Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

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AUG 13 2010

Re: k092875
Trade/Device Name: Echo TD-3227 Dual Blood Pressure/Blood Glucose Meter
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA, NBW, DXN
Dated: July 23, 2010
Received: July 26, 2010

Dear Ms. Liang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K092875

Attachment 6. Indications for Use

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Indications for Use

510(k) Number: K092875

Device Name: **ECHO TD-3227 Dual Blood Pressure/Blood Glucose Meter**

Indications for Use:

ECHO TD-3227 Dual Blood Pressure/Blood Glucose Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the following alternative sites: the palm, forearm, upper-arm, calf and thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. The alternative site testing in the systems can be used only during steady-state blood glucose conditions.

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The device is not to be used for the diagnosis or screening of diabetes, hypertension or for testing on neonates.

Prescription Use _____ And/Or Over the Counter Use __X__

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K092875